Reuse of Single Use Devices: FDA's Regulatory Requirements for Third Party and Hospital Reprocessors

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Presented at: RAPS 2001 Annual Conference
Baltimore, MD
November 5, 2001

Objectives

- Development of FDA's reuse policy or "how we got where we are"
- Principles underlying the reuse policy
- List of regulatory requirements
- Important dates
- Premarket submissions received to date
- Some issues that FDA has encountered

"How we got where we are" Congressional interest-106th Congress

- Sen. Durbin introduced *Reprocessed Single Use Medical Devices Patient Safety Amendments of 1999* (S 1542)

- Reps. Eshoo & Upton introduced *Reprocessed Single Use Medical Device Patient Safety Act of 1999* (HR 3148)

Congressional interest continued …

- Feb 10, 2000: House Committee on Commerce's hearing on reuse policy

- Jun 27, 2000: Senate Committee on Health, Ed., Labor & Pension's hearing on the General Accounting Office's (GAO) report *Reprocessing and Reuse of Devices Labeled Single Use* (www.gao.gov)

Results of FDA's in-house research

Lead researchers: K. Merritt, V. Hitchins, S. Brown, T. Woods, Office of Science & Technology

- PTCA catheters
  - many catheters were difficult to clean
  - some balloons became less compliant with repeated reuse or ETO sterilization
  - effect of reprocessing and reuse are model specific

Results of FDA's research continued ...

- GI Biopsy Forceps
  - cleaning with a sequence of bleach, ultrasonic bath of detergent and enzyme, and water rinse appears to remove residual debris
  - drying the lumen is difficult

Results of FDA's research continued ...

- Synthetic Absorabable Sutures
  - repeated ETO sterilization of O-B-U sutures
  - some inner packs were destroyed leading to exposure to ambient humidity
  - may eventually lead to suture degradation and loss of strength

Enforcement Priorities for Single Use Devices Reprocessed by Third Parties and Hospitals

August 14, 2000

www.fda.gov/cdrh/comp/guidance/1168.pfd

Principles underlying FDA's reuse policy

- Reprocessing is a manufacturing activity;
- FDA will regulate original equipment manufacturers and all SUD reprocessors in the same manner; and
- FDA's primary goal is to protect public health by assuring that reprocessed SUDs are as safe and effective as new SUDs.

FDA's regulatory requirements for SUD reprocessors

- Registration & Listing (21 CFR Part 807)
- MDR Regulation (21 CFR Part 803)
- Medical Device Tracking (21 CFR Part 821)
- Corrections & Removals (21 CFR Part 806)
- Quality System Regulation (21 CFR Part 802)
- Labeling Regulation (21 CFR Part 801)
- Premarket Notification & Approval Requirements (21 CFR Parts 807 & 814)

Important dates for SUD reprocessors

February 14, 2001

- Deadline for submission of a premarket approval application (PMA) or a premarket notification (510(k)) for a class III SUD

Important dates continued ...

August 14, 2001

- Deadline for submission of 510(k)s for non-exempt class II SUDs

- Deadline for hospital reprocessors to register & list with FDA

Important dates continued ...

February 14, 2002

- Deadline for submission of 510(k)s for non-exempt class I SUDs
- Deadline for 510(k) clearance for non-exempt class II SUDs
- Deadline for 4 reprocessors to obtain PMA approval for cardiac ablation catheters*

Important dates continued ...

August 14, 2002

- Deadline for 510(k) clearance for non-exempt class I SUD

- Deadline for hospital reprocessors to comply with MDR, tracking, corrections & removals, labeling, and quality system regulation*

PMAs & 510(k)s submitted

- 4 PMAs for cardiac ablation catheters under review
- 89 510(k)s received for non-exempt class II SUDs under review

Some issues that FDA has encountered

- Time allotted to reprocessors to obtain PMA approval for class III SUDs (SterilMed's Citizen Petition)*
- Hospital are unable to comply with postmarket requirements by August 14, 2001 (AHA, Mayo & AAOS letter to the Secretary)*
- Appropriate labeling for reprocessed SUDs (ADDM's Citizen Petition)

FDA Internet site on reuse

www.fda.gov/cdrh/reuse/index.shtml